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## NOTICE OF ALLOWANCE AND FEE(S) DUE

23579 7590 05/28/2009

Pabst Patent Group LLP  
1545 PEACHTREE STREET NE  
SUITE 320  
ATLANTA, GA 30309

EXAMINER	
VU, QUYNH-NHU HOANG	
ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 05/28/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,695	01/16/2004	Gerianne Tringali DiPiano	FEM 105	8448

TITLE OF INVENTION: VAGINAL OR RECTAL APPLICATOR

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	08/28/2009

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.**

**THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.**

### HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

## PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail Stop ISSUE FEE**  
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

23579 7590 05/28/2009

Pabst Patent Group LLP  
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SUITE 320  
ATLANTA, GA 30309

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

### Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)

(Signature)

(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,695	01/16/2004	Gerianne Tringali DiPiano	FEM 105	8448

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nonprovisional	NO	\$1510	\$300	\$0	\$1810	08/28/2009
EXAMINER	ART UNIT	CLASS-SUBCLASS				
VU, QUYNH-NHU HOANG	3763	604-275000				

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.  
 "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,  
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 \_\_\_\_\_  
2 \_\_\_\_\_  
3 \_\_\_\_\_

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent):  Individual  Corporation or other private group entity  Government

4a. The following fee(s) are submitted:

Issue Fee  
 Publication Fee (No small entity discount permitted)  
 Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

A check is enclosed.  
 Payment by credit card. Form PTO-2038 is attached.  
 The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.  b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature \_\_\_\_\_

Date \_\_\_\_\_

Typed or printed name \_\_\_\_\_

Registration No. \_\_\_\_\_

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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10/759,695	01/16/2004	Gerianne Tringali DiPiano	FEM 105	8448
23579	7590	05/28/2009	EXAMINER	
VU, QUYNH-NHU HOANG				ART UNIT
3763				PAPER NUMBER
DATE MAILED: 05/28/2009				

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 342 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 342 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/759,695	DIPIANO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	QUYNH-NHU H. VU	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 2/13/09 & 4/24/09.
2.  The allowed claim(s) is/are 1,3-6,9 and 11-13.
3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All
  - b)  Some\*
  - c)  None
  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_.
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

#### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with attorney Rivka Monheit on 4/24/09.

The application has been amended as follows:

#### **IN THE CLAIMS**

1. (Currently amended) A vaginal applicator for transvaginal drug delivery comprising
  - (a) an applicator barrel, wherein the applicator barrel has a size and shape suitable for insertion into the vagina, preventing penetration of the vaginal wall or cervix, and delivering a pharmaceutical composition to the upper vaginal vault,  
wherein the applicator barrel comprises a medication chamber at the proximal end of the applicator,  
wherein the medication chamber has a smaller diameter than the inner diameter of the applicator barrel and defines a cavity within the applicator barrel having a volume of 1 mL or less, wherein there is a space between the applicator barrel and the medication chamber, wherein the medication chamber is designed to contain 1 mL or less of the pharmaceutical composition in a form selected from the group consisting of powder, gel, cream, and lotion, wherein the proximal end of the applicator contains an opening suitable for filling the medication chamber with the pharmaceutical composition and dispensing the pharmaceutical composition from the medication chamber, wherein the medication chamber comprises a dispensing end that cannot extend past the proximal end of the applicator barrel, and wherein the applicator barrel comprises a barrier proximal to the opening;
  - (b) a plunger, wherein the plunger is insertable in telescoping relation to the applicator barrel until the plunger reaches the barrier wherein the proximal end of the plunger comprises a plunger tip;

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- (c) a flange at the distal end of the applicator; and
- (d) an applicator cap, wherein the applicator cap is removable from the proximal end of the applicator barrel.

Claim 2. (Cancelled)

3. (Previously presented) The vaginal or rectal applicator of claim 1, wherein the applicator cap has a diameter that is effective at preventing insertion of the vaginal applicator into a vagina when the applicator cap is attached to the applicator barrel.

4. (Original) The vaginal or rectal applicator of claim 1, wherein the applicator cap forms an air-tight seal with the applicator barrel.

5. (Original) The vaginal or rectal applicator of claim 1, wherein the plunger tip forms an air-tight seal with the applicator barrel.

6. (Currently amended) A method of transvaginal drug delivery comprising

(1) breech filling a vaginal applicator with 1 mL or less of a pharmaceutical formulation, wherein the vaginal applicator comprises

(a) an applicator barrel, wherein the applicator barrel has a size and shape suitable for insertion into the vagina, preventing penetration of the vaginal wall or cervix and delivering the pharmaceutical formulation to the upper vaginal vault, wherein the applicator barrel comprises a medication chamber at the proximal end of the applicator, wherein the medication chamber has a smaller diameter than the inner diameter of the applicator barrel and defines a cavity having a volume of 1 mL or less, wherein there is a space between the applicator barrel and the medication chamber, wherein the medication chamber comprises a dispensing end that cannot extend past the proximal end of the applicator barrel, and wherein the applicator barrel comprises a barrier proximal to the opening;

(b) a plunger, wherein the plunger is insertable in telescoping relation to the applicator barrel until the plunger reaches the barrier, wherein the proximal end of the plunger comprises a plunger tip; and

(c) a flange at the distal end of the applicator;

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(2) inserting the applicator barrel into a patient's vagina, wherein the pharmaceutical formulation is in a form selected from the group consisting of a powder, gel, cream, and lotion, and

(3) depressing the plunger until it reaches the barrier to administer all of the pharmaceutical formulation to the patient's upper vaginal vault.

Claims 7-8. (Canceled).

9. (Previously presented) The method of claim 6, wherein the pharmaceutical formulation is in an amount effective to treat disorders and diseases of the female urogenital system, cervix, uterus, ovaries, fallopian tubes, and peritoneal cavity.

Claim 10. (Canceled)

11. (Previously presented) The method of claim 6, further comprising, after step (1) and prior to step (2), placing an applicator cap on the proximal end of the applicator barrel and then removing the applicator cap from the proximal end of the applicator barrel.

12. (Previously presented) The applicator of claim 1, wherein the applicator has a rounded tip at the proximal end of the applicator.

13. (Previously presented) The method of claim 6, wherein the applicator has a rounded tip at the proximal end of the applicator.

#### **ALLOWABLE SUBJECT MATTER**

Claims 1, 3-6, 9, 11-13 are allowed over the prior art of record as amended in this office action.

The following is an examiner's statement of reasons for allowance: the claims in this application have been allowed because the prior arts of record fail to disclose either singly or in combination the claimed of a vaginal applicator and a method for transvaginal drug delivery comprising: wherein the applicator barrel comprises a medication chamber at the proximal end of the applicator,

wherein the medication chamber has a smaller diameter than the inner diameter of the applicator barrel and defines a cavity within the applicator barrel having a volume of 1 mL or less, wherein there is a space between the applicator barrel and the medication chamber, wherein the medication chamber is

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designed to contain 1 mL or less of the pharmaceutical composition in a form selected from the group consisting of powder, gel, cream, and lotion, wherein the proximal end of the applicator contains an opening suitable for filling the medication chamber with the pharmaceutical composition and dispensing the pharmaceutical composition from the medication chamber, wherein the medication chamber comprises a dispensing end that cannot extend past the proximal end of the applicator barrel, and wherein the applicator barrel comprises a barrier proximal to the opening;

The closest prior arts, Jones (US 2,847,011) and Dash (US 3,850,173) discloses conventional a vaginal applicator for transvaginal drug delivery, either singularly or in combination, fail to anticipate or render the above limitations obvious.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu  
Examiner  
Art Unit 3763